DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 30, 2014

PHADIA US, INC.
C/O MR. MARTIN ROBERT MANN
SENIOR REGULATORY AFFAIRS MANAGER
4169 COMMERCIAL AVENUE
PORTAGE, MI 49002

Re: k140493
Trade/Device Name: EliA™ Scl-70^{S} Immunoassay
Regulation Number: 21 CFR §866.5100
Regulation Name: Antinuclear Antibody Immunological Test System
Regulatory Class: Class II
Product Code: LJM
Dated: September 24, 2014
Received: September 26, 2014

Dear Mr. Mann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and
Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140493

Device Name
EliA™ Scl-70s

Indications for Use *(Describe)*
EliA Scl-70s is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to Scl-70 in human serum and plasma (heparin, EDTA) as an aid in the clinical diagnosis of scleroderma (diffuse form) in conjunction with other laboratory and clinical findings. EliA Scl-70s uses the EliA IgG method on the instrument Phadia 100.

EliA Scl-70s is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to Scl-70 in human serum and plasma (heparin, EDTA) as an aid in the clinical diagnosis of scleroderma (diffuse form) in conjunction with other laboratory and clinical findings. EliA Scl-70s uses the EliA IgG method on the instrument Phadia 250.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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D.1 510k Summary long EliA Scl-70^S

510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION SUMMARY

A. 510(k) Number:
k140493

B. Purpose for Submission:
New devices

C. Measurand:
IgG Antibodies to Scl-70

D. Type of Test:
Semi-quantitative immunofluorescence assay

E. Applicant:
Phadia US Inc.

F. Proprietary and Established Names:
EliA™ Scl-70^S Well

G. Regulatory Information:

1. Regulation section:
   21 CFR §866.5100, Antinuclear antibody immunological test system

2. Classification:
   Class II (Assay)

3. Product code:
   LJM Antinuclear Antibody (Enzyme-Labeled), Antigen, Controls|

4. Panel:
   Immunology

H. Intended Use:

1. Intended use(s):

   EliA Scl-70^S is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to Scl-70 in human serum and plasma (heparin, EDTA) as an aid in the clinical diagnosis of scleroderma (diffuse form) in conjunction with other laboratory and clinical findings. EliA Scl-70^S uses the EliA IgG method on the instrument Phadia 100.

   EliA Scl-70^S is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to Scl-70 in human serum and plasma (heparin, EDTA) as an aid in the clinical diagnosis of scleroderma (diffuse form) in conjunction with other laboratory and clinical findings. EliA Scl-70^S uses the EliA IgG method on the instrument Phadia 250.

2. Indication(s) for use:
   Same as intended use

3. Special conditions for use statement(s):
   For prescription use only

4. Special instrument requirements:
   Phadia® 100, Phadia® 250

I. Device Description:

- EliA Scl-70^S Wells (14-5637-01) are coated with a human recombinant Scl-70 protein – 4 carriers, (12 wells each), ready to use

The method-specific reagents on Phadia 100 and Phadia 250 are identical; they are only filled in different containers.

Needed reagents for Phadia 100:

- EliA Sample Diluent, method-specific, PBS containing BSA, detergent and 0.095% sodium azide – ready to use; (83-1003-01)
- EliA IgG Conjugate, β-galactosidase labeled anti-IgG (mouse monoclonal antibodies) in PBS containing BSA, detergent and 0.06% sodium azide – ready to use; (83-1002-01, 83-1005-01)
- EliA ANA Positive Control 100: containing IgG antibodies to dsDNA, RNP, Sm, Ro, La, Scl-70, CENP and Jo-1, 6 single-use vials, 0.3 mL each, ready to use; (83-1038-01)
- EliA IgG/IgM/IgA Negative Control 100: containing normal human serum from healthy donors – 6 single-use vials, 0.3 mL each, ready to use; (83-1042-01)
- EliA IgG Calibrators, human IgG in PBS (0, 4, 10, 20, 100, 600 µg/L) – 6 single-use vials, 0.3 mL each, ready to use; (83-1000-01)
- EliA IgG Curve Control, human IgG (20 µg/L) in PBS, 6 single-use vials, 0.3 mL each, ready to use; (83-1001-01)
- EliA IgG Calibrator Wells are coated with mouse monoclonal antibodies - 4 carriers, (12 wells each), ready to use; (14-5509-01)

Needed reagents for Phadia 250:

- EliA Sample Diluent, method-specific, PBS containing BSA, detergent and 0.095% sodium azide – ready to use; (83-1023-01)
- EliA IgG Conjugate, β-galactosidase labeled anti-IgG (mouse monoclonal antibodies) in PBS containing BSA, detergent and 0.06% sodium azide – ready to use; (83-1017-01, 83-1018-01)
- EliA ANA Positive Control 250: containing IgG antibodies to dsDNA, RNP, Sm, Ro, La, Scl-70, CENP and Jo-1, 6 single-use vials, 0.3 mL each, ready to use; (83-1033-01)
- EliA IgG/IgM/IgA Negative Control 250: containing normal human serum from healthy donors – 6 single-use vials, 0.3 mL each, ready to use; (83-1037-01)
- EliA IgG Calibrator Strips, human IgG in PBS (0, 4, 10, 20, 100, 600 µg/L) – 6 single-use vials, 0.3 mL each, ready to use; (83-1015-01)
- EliA IgG Curve Control Strips, human IgG (20 µg/L) in PBS, 6 single-use vials, 0.3 mL each, ready to use; (83-1016-01)
- EliA IgG Calibrator Wells are coated with mouse monoclonal antibodies - 4 carriers, (12 wells each), ready to use; (14-5509-01)

The Phadia EliA immunodiagnostic system is automated system for immunodiagnostic testing. The EliA reagents are available as modular packages, each purchased separately. All packages except the positive and negative controls are required to carry out an EliA Scl-70^S test.

J. Substantial Equivalence Information:

1. Predicate device name(s) and 510(k) number(s):
   QuantaLite™ Scl-70 ELISA, INOVA K924988

2. Comparison with predicate:

Similarities to predicate device

Feature	Predicate Device INOVA QuantaLite Scl-70 ELISA	New Device EliA Scl-70^S
Intended Use	QUANTALite Scl-70 is an enzyme-linked immunosorbent assay (ELISA) for the semi-quantitative detection of Scl-70 antibodies in human serum. The presence of Scl-70 antibodies can be used in conjunction with clinical findings and other laboratory tests to aid in the diagnosis of scleroderma.	EliA Scl-70^S is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to Scl-70 in human serum and plasma (heparin, EDTA) as an aid in the clinical diagnosis of scleroderma (diffuse form) in conjunction with other laboratory and clinical findings. EliA Scl-70^S uses the EliA IgG method on the instruments Phadia 100 or Phadia 250.
Internal Controls	Low Positive, High Positive and Negative Control included in the kit	Positive and negative Control provided with the EliA ANA Positive Control 100 / 250 and EliA IgG/IgM/IgA Negative Control 100 / 250, respectively
Assay Type	ELISA	
Type of test	Semi-quantitative	
Solid Phase	Microwells	

Differences to predicate device

Feature	Predicate Device INOVA QuantaLite Scl-70 ELISA	New Device EliA Scl-70^S
Antigen used	purified Scl-70 antigen	Human recombinant Scl-70 protein
Instrumentation	ELISA-Reader needed	Phadia 100, Phadia 250 are fully automated immunoassay analyzers
Reaction temperature	Room temperature, 20-26°C	37°C controlled
Incubation times	High positive, low positive and negative Controls, diluted patient samples: 30 min. Conjugate: 30 min. Substrate: 30 min (in dark).	Diluted patient samples: 30 min. Conjugate: 28 min. Development Solution: 39 min.
Detection antibody (conjugate)	IgG conjugate: anti-human IgG horse radish peroxidase (goat)	IgG conjugate: anti-human IgG ß-Galactosidase (mouse monoclonal antibodies)
Signal	Optical density (at 450nm)	Fluorescence
Calibration	1-point Calibration	Total IgG Calibration
Calibrators	n.a.	6 vials of human IgG at concentrations of 0 – 4 – 10 – 20 – 100 - 600 µg/l
Calibration curve	n.a.	Option to store curve for up to 28 days and run curve controls in each assay for calibration
Concept	All reagents in a single kit	Modular reagents concept (test-method specific and general

Feature	**Predicate Device** INOVA QuantaLite Scl-70 ELISA	**New Device** EliA Scl-70^S
		reagents)
Sample Dilution	1:101	1:100
Reported Unit	Units	EliA U/ml
Cut-off	< 20 Units negative 20-39 Units weak positive 40-80 Units moderate positive > 80 Units strong positive	< 7.0 EliA U/ml negative 7.0-10.0 EliA U/ml equivocal > 10.0 EliA U/ml positive
Substrate	TMB Chromogen	Development Solution 0.01 % 4-Methylumbelliferyl-β-D-galactoside & <0.0010% pre-servative (mixture of 5-chloro-2-methyl-2H-isothiazol-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1))

K. Standard/Guidance Document Referenced (if applicable):

CLSI EP17-A, Protocols for Determination of Limits of Detection and Limits of Quantification, Approved Guideline.

L. Test Principle:

The EliA Scl-70^S Wells are coated with human recombinant Scl-70 protein. If present in the patient's specimen, antibodies to Scl-70 bind to their specific antigen. After washing away non-bound antibodies, enzyme-labeled antibodies against human IgG antibodies (EliA IgG Conjugate) are added to form an antibody-conjugate complex. After incubation, non-bound conjugate is washed away and the bound complex is incubated with a Development Solution. After stopping the reaction, the fluorescence in the reaction mixture is measured. The assay directly measures the amount of antibody of interest bound to the antigen coating the EliA well, therefore the higher the value of fluorescent signal detected by the instrument, the higher the amount of antibody bound and detected in the sample tested. To evaluate test results, the response for patient samples is compared directly to the response for calibrators.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

To determine the precision of the assays on Phadia 100 and Phadia 250 instruments, the variability was assessed on 3 samples. One batch was used to determine the precision of the assays on Phadia 100.
Three batches were used to determine the precision of the assays on Phadia 250 (equal to 252 replicate determinations per sample). The results are summarized in the tables below:

To determine the precision of the assays, the variability was assessed in a study with a total of 21 runs (3 instruments x 7 runs each) over 7 days performed on samples with 84 replicate determinations per sample with a calibration curve in each run.

EliA Scl-70^S on Phadia 100 (n=84)

Mean value EliA U/ml	Intra-Run CV%	Inter-Run CV%	Total %CV
8.8	2.89	2.06	3.55
30.2	3.21	2.41	4.01
193.0	4.90	3.51	6.03

To determine the precision of the assay, the variability was assessed in a study with a total of 21 runs (3 instruments x 7 runs each) over 7 days performed on samples with 252 replicate determinations per sample with a calibration curve in each run.

EliA Scl-70^S on Phadia 250 (n = 252)

Mean value EliA U/ml	Intra Run CV%	Inter Run CV%	Total %CV	Lot to Lot CV%
7.5	3.08	1.25	3.33	1.07
28.2	2.71	2.26	3.53	2.01
200.1	4.46	3.05	5.40	5.27

b. Linearity/assay reportable range:

Four patient serum samples were diluted in sample diluent and tested with one batch of EliA Scl-70^S with one set of system reagents on Phadia 100 or Phadia 250. The ratios of observed/expected values and least square linear regressions were calculated. The results are summarized below:

EliA Scl-70^S on Phadia 100

Dilution range (EliA U/ml)	Slope	Intercept	R^2
172.3 - 1.8	1.112	-0.902	1.00
185.5 - 2.1	0.995	0.151	1.00
192.0 - 2.1	1.062	0.300	1.00
28.1 - 0.1	0.960	-0.142	1.00
297.1 - 2.9	1.101	-1.134	1.00

EliA Scl-70^S on Phadia 250

Dilution range (EliA U/ml)	Slope	Intercept	R^2
207.7 - 1.9	0.961	-0.399	1.00
159.9 - 1.4	1.088	0.655	1.00
193.6 - 2.1	1.062	0.047	1.00
24.3 - 0.2	1.041	0.040	1.00
298.9 - 3.1	1.088	0.653	1.00

The claimed linear range for EliA Scl-70^S is 0.6 – 297.1 EliA U/ml (0.6 is the limit of detection).

HookEffect/OvertheRangeResults:

Hook effect was investigated by using a serum sample above the highest calibration point. A high positive sample was diluted and the dilutions were measured in four replicates and compared to Cal-600 (600 µg/L).

No hook effect was observed when analyzing a high positive sample that had a concentration up to 14 times above the upper limit of the technical measuring range.

Results above the upper limit of the measuring range are reported as “above”. No recommendations are made for dilution of samples outside measuring range in the Package Insert.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability:

The IgG calibrators are traceable (via unbroken chain of calibrations) to the International Reference Preparation (IRP) 67/86 of Human Serum Immunoglobulins A, G and M from WHO. New batches of IgG calibrators are compared to a secondary standard (standardized with the IRP) or the IRP directly and adjusted accordingly to meet the correct concentration.

The instrument measures specific IgG concentrations in µg/l. By using a conversion factor given as bar code on the EliA well, the results are automatically converted to EliA U/mL for EliA Scl-70^S.

Stability:

The EliA IgG system reagents EliA ANA Positive Control and the EliA IgG/IgM/IgA Negative Control are already FDA cleared under k063775, k072393, and k091845, respectively.

Shelf life:
Accelerated study was done to determine the shelf life EliA Scl-70^S Wells and was determined to be 18 months at 2-8°C. The real time stability test confirms the determined shelf life.

On-board stability:
The on-board stability EliA Scl-70^S carriers was tested over 4 weeks using 3 positive and 2 negative samples only on the Phadia 250 instrument since for Phadia 100 the reagents are stored off the instrument and are only loaded as needed for an assay. The on-board stability for the Phadia 250 instrument was determined to be 28 days at 2-8°C.

Open Stability:
Accelerated study was done to determine the shelf life EliA Scl-70^S Wells after first opening of the foil bag containing the EliA Scl-70^S Wells. It was determined to be 9 months at 2-8°C. The real time stability test confirms the determined shelf life.

d. Detection limit:
The limit of blank (LoB) and limit of detection (LoD) studies were done on both Phadia 100 and Phadia 250. Six blood donors with low/negative antibody concentration were measured in twelve replicates in each of six runs on six different days (12 replicates x 6 runs x 6 days = 432 replicates per sample). The six runs for each system, Phadia 100 and Phadia 250, were spread over two instruments. The results are summarized in the tables below:

EliA Scl-70^S (EliA U/mL)	LoB	LoD
Phadia 100	0.25	0.36
Phadia 250	0.31	0.52

It was decided to use a single LoD of 0.6 U/mL for both instruments.

e. Analytical specificity:
Endogenous Interference:
A study was run to investigate whether high concentrations of potentially interfering substances in serum, like bilirubin, hemoglobin, chyle and rheumatoid factor adversely affect the results of the new device. Five serum samples were prediluted in EliA Sample Diluent and spiked with the different interfering substances or their respective blank solutions, and analyzed in triplicates. The runs were repeated twice. One batch of EliA antigen wells and one batch of system reagents were used throughout the studies.

Two negative, two samples with concentrations around the cut-off and one positive sample were tested. The ratio of blank/spiked sample was 0.94 – 1.09. No interference was observed up to the concentrations listed in the table below:

Potential Interfering Compound	Concentration in undiluted sample
Bilirubin F	19.2 mg/dl
Bilirubin C	20.1 mg/dl
Hemoglobin	496 mg/dl
Chyle (ClinOleic)	1%
Rheumatoid factor	500 IU/ml

Carry-over:
Carry over is a technical phenomenon that is due to the instrumentation. The instrumentation is identical for all EliA tests (Phadia instruments). Also the basic circumstances of the test are identical between EliA Ro and the newly submitted EliA test (same source of test material, same reagents, same magnitude of specific antibody concentration etc.). Thus, results obtained with one EliA test can be transferred to any other EliA serum test.

A study was carried out on a Phadia 250 instrument using the test EliA Ro, cleared under k082759. A serum sample was diluted 1:2 and 1:20 using instrument dilution and manual dilution. A lower dilution factor than the default one (1:100) was chosen to challenge the system. Only a few RUs difference compared to the reference pipetting could be seen, which is too low to be expressed in EliA U/ml.
The observed carry over effect is therefore negligible without any influence to assay results.

f. Assay cut-off:
A study was done on 400 apparently healthy blood donor samples from Caucasian individuals equally distributed by sex and age in order to evaluate expected values in the normal population and to confirm the defined cut-off. The samples were measured on the Phadia 250 instrument for EliA Scl-70^S. The 99th percentile of the 400 samples were calculated and taken into account for setting of the cut-off. The following values were selected for the cut-off:

EliA Scl-70^S	
<7 EliA U/mL	Negative
7 — 10 EliA U/mL	Equivocal
>10 EliA U/mL	Positive

In case of equivocal results, it is recommended to retest the patient after 8-12 weeks.

2. Comparison studies:

a. Method comparison with predicate device:
A total of 390 serum samples were collected from patients with diagnosis of Scleroderma (SSc, n = 101), limited cutaneous form of systemic sclerosis (CREST, n = 33), Mixed connective tissue disease (MCTD, n = 37), Systemic lupus erythematodes (SLE, n = 34), Sjögren's syndrome (SS, n = 26), Poly/Dermatomyositis (PM/DM, n = 5), Rheumatoid arthritis (RA, n = 30), various cancers (n = 20), various bacterial infections (n = 24), various viral infections (n = 26), technical samples positive or equivocal for EliA Scl-70^S (n = 54).

Samples were analyzed with the EliA Scl-70^S and INOVA QuantaLite^{TM} Scl-70 ELISA assays. The test was run in single determination and values outside the linear measuring range (n=16) were excluded from statistical analyses for the technical agreement. The results are summarized in the tables below:

Equivocal results evaluated as negative:

		QuantaLite Scl-70 ELISA (Units)		
		Positive >20	Negative <20	Total
EliA Scl-70^S (EliA U/mL)	Positive >10	51	9	60
	Negative ≤10	6	308	314
	Total	57	317	374

Positive percent agreement: **89.5%** (95% CI: 77.8 – 95.6%)
Negative percent agreement: **97.2%** (95% CI: 94.5 – 98.6%)
Total percent agreement: **95.9%** (95% CI: 93.3 – 97.7%)

Equivocal results evaluated as positive:

		QuantaLite Scl-70 ELISA (Units)		
		Positive >20	Negative <20	Total
EliA Scl-70^S (EliA U/mL)	Positive >10	53	21	74
	Negative ≤10	4	296	300
	Total	57	317	374

Positive percent agreement: **93.0%** (95% CI: 82.2 – 97.8%)
Negative percent agreement: **93.4%** (95% CI: 89.9 – 95.8%)
Total percent agreement: **93.3%** (95% CI: 90.2 – 95.5%)

b. Matrix comparison:
Serum, lithium heparin plasma, and EDTA plasma were collected from the same patients (n = 50) to demonstrate that the plasma results do not deviate from the corresponding serum results and are within the pre-defined specifications.
Samples were spiked with a serum sample of high antibody titer to cover the measuring range. Samples were tested in duplicates. Passing & Bablok regression plots were generated using the first replicate only and by plotting the concentration observed from the control tube (serum) versus the concentration for each test collection tube. The corresponding slopes of regression and coefficient determination are summarized in the tables below:

	Range tested (EliA U/mL)	Slope (95% CI)	Intercept (95% CI)	R^2
Serum vs heparin plasma	0.6 — 278.9	1.05 (1.03 to 1.07)	-0.08 (-0.24 to +0.17)	1.00
Serum vs EDTA plasma	0.6 — 264.2	1.00 (0.99 to 1.02)	-0.05 (-0.29 to +0.21)	1.00

c. Instrument comparison
Performance of EliA Scl-70^S was evaluated on the Phadia 100 and Phadia 250 instruments using 24 positive, 8 equivocal and 4 negative samples. The samples were analyzed in six runs in single replicates on three Phadia100 and three Phadia 250 instruments, with 2 runs on each instrument. The regression analysis results are summarized as follows:

	Intercept	Slope
Estimate	-0.07	0.96
95% CI	-0.52 – 0.14	0.94 – 0.99

3. Clinical studies:

a. Clinical Sensitivity and specificity:
336 clinically defined sera from patients with scleroderma or other connective tissue diseases, bacterial or viral infections, cancer or rheumatoid arthritis were tested on EliA Scl-70^S as laid out in the respective Directions for Use

Test results of EliA Scl-70^S with 336 clinically defined samples. The diagnostic group of Scleroderma diagnosed patients (SSc) is the positive target group. Equivocal results evaluated as negative:

	Diagnostic Group – SSc		
	+ / SSc	- / Controls*	total
Positive test >10 EliA U/mL	31	3	**34**
Negative test ≤10 EliA U/mL	70	232	**302**
Total	**101**	**235**	**336**

Sensitivity: **30.7%** (95% CI: 22.1% – 40.8%)
Specificity: **98.7%** (95% CI: 96.0% – 99.7%)

The table below shows the positive results for each clinical subgroup. Equivocal results evaluated as negative:

Disease	Total number of samples	**Number & percentage of positive samples**			
		QuantaLite Scl-70		**EliA Scl-70^S**	
SSc	101	29	29%	31	31%
CREST	33	2	6%	2	6%
MCTD	37	0	0%	0	0%
SLE	34	1	3%	0	0%
SS	26	1	4%	1	4%
PM/DM	5	0	0%	0	0%
RA	30	0	0%	0	0%
Cancer	20	0	0%	0	0%
Infections	50	2	4%	0	0%

SSc: Scleroderma, CREST: limited cutaneous form of systemic sclerosis, MCTD: Mixed connective tissue disease, SLE: Systemic Lupus Erythematosus, SS: Sjögren's syndrome- systemic sclerosis, PM/DM: Poly-/Dermatomyositis, RA: Rheumatoid arthritis, Cancer: various cancers, Infections: various bacterial and viral infections.

b. Other clinical supportive data (when a. is not applicable):
Not applicable

4. Clinical cut-off:
   Same as assay cut-off

5. Expected values/Reference range:
   Antibody prevalence in autoimmune patients varies widely depending on disease area. The proportion of sera from a normal population found positive for Scl-70 antibodies covered by the EliA Scl-70^S test is below 1 %. Expected values may vary depending on the population tested.